K121290

510(k) Section 5
Pre-filled Lube Jel Syringe

AUG 10 2012

5 – 510(k) Summary
(In accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. **Submitter's name and address:**
   Nurse Assist Incorporated
   3400 Northern Cross Boulevard
   Fort Worth, Texas 76137

2. **Submitter's telephone number and fax number:**
   Tel: (817) 231-1300
   Fax: (817) 231-1500

3. **Contact person:**
   Bill Kanewske - Vice President of Operations

4. **Date this 510(k) summary prepared:**
   04/27/2012

5. **Trade/proprietary name of the device:**
   Sterile Lube Jelly Pre-Filled Syringe

6. **Device classification**
   Classification Name – Patient Lubricant (21 CFR 880.6375)
   Class 1
   Product code KMJ

7. **Legally marketed predicate devices to which substantial equivalence is claimed:**
   Steri-Lub Lubrication Gel; Horizon Medical, Inc. – K944969

8. **Description of the device that is the subject of this premarket notification:**
   The subject device is a terminally gamma sterilized 10cc polypropylene plastic syringe filled with United Guardian lubricating jel and capped with a polypropylene plastic cap. United Guardian has a Master File Reference for its lubrication jel, Master File for Devices MAF-613 pertaining to Lubrajel RR. All components of the device are gamma irradiation stable.

9. **Intended use and indication for use:**
   For Prescription Use: For easing the insertion of medical devices such as scopes and catheters into body orifices.

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10. Technological characteristics:

A comparison between the Nurse Assist Lube Jelly Pre-Filled Syringe and the Horizon Lube Jelly Pre-Filled Syringe is provided in the table below.

	Nurse Assist Lube Jelly Pre-Filled Syringe	Horizon, Steri-Lub Lubrication Gel
Classification Product Code	KMJ	KMJ
Intended use: Lubricating Device Insertion	X	X
Prescription	X	X
Sterile?	Yes	Yes
Shelf life	2 years	2 years
Chemical composition	Water, Glycerin, Polyacrylic Acid, Propylene Glycol, and Sodium Polyacrylate preserved with methyl and propyl paraben and sodium metabisulfite	Water, Glycerin, Polyacrylic Acid, Propylene Glycol, and Sodium Polyacrylate preserved with methyl and propyl paraben and sodium metabisulfite
Mechanism of dispensing	10cc Plastic Syringe, Oral Tip	10cc Plastic Syringe, Oral Tip
Barrel, Plunger, Tip Cap Material	Polypropylene	Polypropylene
Plunger Grommet Material	This product is not made with natural rubber latex	This product is not made with natural rubber latex

11. Non-Clinical Performance Data

Sterile Lube Jelly Pre-Filled Syringe, product number 1104, is packaged in a 10cc syringe. Testing was performed to demonstrate that the syringe remained sealed when exposed to a 15 In-Hg vacuum.

Stain testing was conducted on post sterile product. Testing was performed to demonstrate that the post sterile lubricant did not stain gloves.

Viscosity testing was conducted on post sterile product. Testing was performed to demonstrate that the post sterile lubricant remained within the pre-sterile 18,000 to 26,500 cps viscosity range.

Volume, pH and sterility testing were conducted on post sterile aged product. Testing was performed to demonstrate that the product characteristics remained within specification after the product was exposed to accelerated aging.
Biocompatibility testing was conducted on post sterile product. Testing was conducted to demonstrate compliance with the requirements of ISO 10993.

12. Substantially Equivalent

The above summarized characteristics and performance testing demonstrated similarities to the predicate Horizon Pre-filled Lube Jelly Syringe. In summary the Nurse Assist Pre-filled Lube Jelly Syringe described in this submission is substantially equivalent to the predicate device.

This concludes the 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Mr. Bill Kanewske
Vice President of Operations
Nurse Assist Incorporated
3400 Northern Cross Boulevard
Fort Worth, Texas 76137

Re: K121390
Trade/Device Name: Pre-Filled Lube Jel Syringe
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: KMJ
Dated: July 3, 2012
Received: July 10, 2012

Dear Mr. Kanewske:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

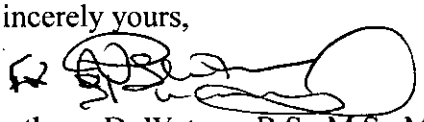
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 – Indications for Use

510(k) Number (if known): K121390
Unknown – not yet assigned by FDA

Device Name: Pre-filled Lube Jel Syringe

Indications for Use:

For Prescription Use:
For easing the insertion of medical devices such as scopes and catheters into body orifices.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/3/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121390